Memorandum

October 30, 1991

From

Nutritionist, Clinical Nutrition Branch, HFF-265

Subject

Documentation for determining reference amounts customarily consumed per eating occasion

To

File

The purpose of this memo is to describe more fully the procedures that FDA used to determine the Reference Amounts Customarily Consumed per Eating Occasion (hereinafter referred to as reference amounts) and to provide detailed calculations, other serving size information, and the rationale that FDA used to establish the reference amount for each of the 131 product categories presented in the 1991 reproposal for serving sizes. To promote uniformity in the reference amounts for similar products regulated by FDA and USDA, representatives from the Food Safety and Inspection Service and the Human Nutrition Information Service of USDA participated in determining the reference amounts.

I. PRINCIPLES CONSIDERED IN DEVELOPING REFERENCE AMOUNTS

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535, hereinafter referred to as the act) defines serving size as an amount customarily consumed which is expressed in a common household measure that is appropriate to the food. The amount customarily consumed is similar in weight or volume, but the customarily consumed amount in household measure often differs for products within the same category because of differences in shapes and sizes. For example, food consumption data show that the amount customarily consumed for vegetables without sauce is about 85 grams (g). A common household measure for this amount of green peas and cut corn would be about 1/2 cup. However, many other vegetables come in a form that cannot be measured with a cup, e.g., brussels sprouts and broccoli spears. A common household measure appropriate for the latter vegetables would be pieces or ounces (oz). Because a uniform household measure cannot be used for all vegetables, the most reasonable approach for this type of food is to establish a reference amount in g and let the manufacturers determine the label serving size in a common household measure that is most appropriate to their specific products.

Therefore, FDA decided to propose reference amounts that represent the amount customarily consumed of all products within a product category. Manufacturers would be required to use the reference amounts to determine the label serving size in common

IOM report (Ref. 15) contained only limited information on serving sizes. Therefore, we used another USDA publication entitled "Good Sources of Nutrients" (Ref. 14) to fill in the missing data on serving sizes from dietary guidance recommendation documents. Although this publication is not specifically for dietary guidance, it provides information on serving sizes on a larger variety of food than the other two USDA dietary guidance documents that the IOM report cited.

Serving sizes recommended in comments on the 1990 proposal and in response to the notice of the public meeting were concerned with the product categories as proposed in the July 19, 1990 proposal. Some of these product categories have been regrouped in the 1991 reproposal. When this happened, we recorded the recommended serving sizes in the appropriate product categories in the reproposal.

D. Procedure for Determining Reference Amounts.

To determine the proposed reference amounts, FDA examined both the survey data (CSS values) obtained by the procedures described in section B and the other information listed in section C above. Using the general guidelines described below, the agency determined the proposed reference amount for each product category.

1. Because the act requires that food consumption data be used as the primary data source for the serving size determination, we first considered food consumption data and whether it provided an appropriate basis from which to derive reference amounts. In deciding whether the data provided an appropriate basis, we considered the adequacy of the sample size and the consistency of the data.

2. Sample size. Adequacy of sample size was classified into three categories: adequate, intermediate, and inadequate.

   (a) Adequate: We believe that a sample size (number of eating occasions) of 140 or larger is large enough to provide reasonable assurance for a reliable estimate of the customarily consumed amount. This sample size is the same as the minimum sample size used by USDA to present the 5th and the 95th percentile values for the NFCS data (Ref. 21). Although the 5th and the 95th percentile values were not used in developing the reference amounts, we used the mode. Many product categories had multiple modes, which, to be reliable, would require a larger sample size than that that would be necessary to ensure the reliability of the mean or the median values. Therefore, to ensure that the modal values were reliable, we used 140 as the cutoff for the

adequate sample size, which is the largest minimum sample size required for presenting the NFCS data (Ref. 21).

(b) Intermediate: We believe that a sample size of 40 through 139 may not be large enough to provide reasonable assurance of a reliable estimate of the customarily consumed amount considering the multiple modes observed for many product categories. The lower cutoff level for the intermediate range (40) is the same as the minimum sample size used by USDA to present the 25th and the 75th percentile values for the NFCS data (Ref. 21).

(c) Inadequate: We believe that a sample size of less than 40 is inadequate to provide reasonable assurance of a reliable estimate of the customarily consumed amount.

3. **Steps followed in selecting survey data**. As mentioned earlier, FDA used both the 1977-1978 NFCS and the 1987-1988 NFCS as the source of food consumption data because the 1987-1988 NFCS could not be used alone given the low response rate in this survey. We used the following guidelines in selecting the survey data for determining the reference amount for each product category:

(a) If the 1987-1988 NFCS data did not substantially differ from the 1977-1978 NFCS data, data from both surveys were used. The use of data from both surveys increased the data points, i.e., provided two sets of the mean, median, and modal CSS values, rather than one set from a single survey. Therefore, the reliability of the reference amount determined was strengthened.

(b) If the 1987-1988 NFCS data suggested a change in consumption practices since the 1977-1978 NFCS (i.e., CSS values increased or decreased), and the validity of the change was supported by the CSFII data, the new survey data were used because the trend change observed in the 1987-1988 NFCS is likely to reflect more current consumed serving sizes.

(c) If the new survey data suggested a change in consumed serving size, but the change was not or could not be supported by the CSFII data, we made our best judgment based on the available evidence.

(d) If appropriate data were not available in the 1977-1978 NFCS, the 1987-1988 NFCS data were used.

selecting the CSS values, other information, judgment, etc.) to determine the reference amount for each product category.

Youngmee K. Park, Ph.D.
Clinical Nutrition Branch, HFF-265
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204
(202) 485-0089

References

1. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual -- Spring Quarter 1977-1978, accession no. PB80-190218/HAE, National Technical Information Service, Springfield, VA, 1980.

2. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual -- Summer Quarter 1977-1978, accession no. PB80-197429/HAE, National Technical Information Service, Springfield, VA, 1980.

3. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual -- Fall Quarter 1977-1978, accession no. PB80-200223/HAE, National Technical Information Service, Springfield, VA, 1980.

4. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual -- Winter Quarter 1977-1978, accession no. PB81-118853/HAE, National Technical Information Service, Springfield, VA, 1981.

5. U.S. Department of Agriculture, Nationwide Food Consumption Survey/Individual Intake - 1987-1988, accession no. PB90-504044, National Technical Information Service, Springfield, VA, 1990.

6. Life Sciences Research Office, "Impact of Nonresponse on Dietary Data from the 1987-1988 Nationwide Food Consumption Survey," Federation of American Societies for Experimental Biology, Bethesda, MD, 1991.